REMARKS

Claims 1-23 are pending. Applicants appreciate the indication that the previous grounds of rejection have been withdrawn.

Applicants address each of the current rejections below in the order in which they appear in the Action.

I. Claims 1-4 and 11-23 Are Patentable Over Makiej in view of Weinstein

Claims 1-4 and 11-23 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,002,048 to Makiej, Jr. (Makiej) in view of U.S. Patent No. 6,382,205 to Weinstein et al. (Weinstein). The Action acknowledges that Makiej does not disclose that the first medicament dispenser is different in type to the at least one further medicament dispenser as recited in claim 1. The Action further appears to acknowledge that Weinstein merely proposes a kit that includes a first medicament dispenser (1) that is different from a second medicament dispenser (2). The Action states at page 3 that "it would have been obvious, to one having ordinary skill in the art at the time of the invention, to modify the device of Makiej so that it would have two separate medicament dispensers, where the first medicament dispenser is different in type from at least one further medicament dispenser, as taught by Weinstein '205, as such a modification would allow a user to use a particular dispenser of the device depending on which dispenser is needed for the situation, as appropriate." Applicants respectfully traverse this rejection.

Claim 1 recites "a unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product, the device comprising

a first medicament dispenser for the delivery of said first medicament; and

at least one further medicament dispenser for the delivery of said at least one further medicament,

wherein said first medicament dispenser and said at least one further medicament dispenser enable the first and the at least one further medicament to be kept separate until the point of delivery, and the first medicament dispenser is different in type to the at least one further medicament dispenser."

The only support given in the Action for modifying Makiej, namely that "such a modification would allow a user to use a particular dispenser of the device depending on which dispenser is needed for the situation, as appropriate" appears to

ignore the recitations in claim 1 of "A unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product . . . ." As described at page 4, lines 6-9, of the specification, "In combination, the first medicament and at least one further medicament comprise a defined combination product. That is to say, that when combined together the distinct active medicament doses released by actuation of the device form a dose of a 'multi-active' medicament treatment." These recitations are neither taught nor suggested by Makiej or Weinstein.

Makiej proposes a device that will assist a patient in maintaining a sequential dosing regimen. For example, at column 2, line 54 through column 3, line 14, Makiej proposes sequential dosing regimens wherein the patient discharges a dose from one of the aerosol MDI containers, waits a predetermined time, then discharges a dose from the other aerosol MDI containers. Makiej does not disclose or suggest "A unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product . . . ." as recited in claim 1. Weinstein does not make up for the shortcomings of Makiej.

Weinstein proposes a method and package for organizing, storing, instructing, and coordinating the combined use of topical medications for the treatment of disorders including respiratory tract disorders for the purpose of reducing medication error and increasing therapeutic compliance. Figure 1 of Weinstein shows a support package 12 that has a first portion 7 and a second portion 8. The second portion 8 houses dosages of a first topical agent 1 and a second topical agent 2. First portion 7 houses an instruction-bearing portion 6 that provides instructions for coordinating use of the first topical agent 1 and the second topical agent 2 as a regimen. (See col. 3, lines 51-64). Topical agent 1 is shown as a nose drops container and topical agent 2 is shown as a nasal aerosol container.

Weinstein neither discloses nor suggests utilizing the two topical agents provided in the kit as a combination medicament product, in which the distinct topical agents combine together to form a combination of the two topical agents. Instead, Weinstein proposes administration of the two topical agents in a sequentially administered regimen. For example, Example 1 of Weinstein at column 4 proposes the use of topical nasal saline aerosol or drops followed by topical intranasal corticosteroid aerosol. At Example 2, Weinstein proposes the use of a topical nasal decongestant in the form of aerosol or drops followed by a topical intranasal

moisturizing agent. Weinstein neither discloses nor suggests utilizing the two topical agents provided in the kit as a combination medicament product.

Accordingly, Makiej and Weinstein, either taken alone or in combination, do not disclose or suggest "A unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product . . . ." In fact, at page 3, the Action acknowledges that "Makiej/Weinstein do not teach a unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product."

The Action asserts that U.S. Patent No. 3,704,725 to Marand (Marand) makes up for the acknowledged shortcomings of Makiej and Weinstein (see rejection of claims 5-10 at pages 3-4 of the Action). However, contrary to the assertions of the Action, Marand does not disclose or suggest "A unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product . . . ." as recited in claim 1.

Instead, Marand proposes a high pressure propellant dispensing valve having a product container (1) that contains a product or products to be dispensed therefrom, a coupler-aspirator (3), and a propellant cartridge (9). The operation of the high pressure propellant dispensing valve is described at col. 2, lines 39-54 as follows:

> The operator grasps the unit generally around guide 30 and applies force to the top of the propellant cartridge 9 as indicated generally by arrow 20. As propellant cartridge 9 is depressed, coupler-aspirator 3 is moved downwardly. The application of continued force causes both the product container valve 2 and the propellant valve 8 to be opened. Therefore, there is communication of the product through product container valve stem 2a and first flow passage 5 into nozzle 4. Similarly, there is communication of the propellant through propellant valve 7 and second flow passage 6 into nozzle 4. Thus, it will be apparent that the propellant aspirates the product through the coupler-aspirator.

Thus, Marand simply proposes a product container, a separate propellant container, and a high pressure propellant dispensing valve that will allow the propellant from the propellant container to dispense the product from the product container. Marand does not disclose or suggest "A unitary medicament dispenser device for use in the delivery of a first medicament and at least one further medicament as a combination medicament product . . . ." as recited in claim 1.

For at least the foregoing reasons, Applicants respectfully submit that claim 1 is patentable over the cited references and respectfully request that this rejection be withdrawn.

Claims 2, 3, 4, and 11-23 each depend from patentable independent claim 1. For at least this reason and without acquiescing in the Action's rejections of these claims, Applicants respectfully submit that these dependent claims are also patentable and request that these rejections be withdrawn. Applicants expressly reserve the right to argue the separate patentability of one or more of these dependent claims in the future.

II. Claims 5-10 Are Patentable Over Makiej in View of Weinstein and further in View of Marand

Claims 5-10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Makiej in view of Weinstein and further in view of U.S. Patent No. 3,704,725 to Marand, et al. (Marand). Applicants respectfully traverse this rejection.

Claims 5-10 each depend from patentable independent claim 1. For at least this reason and without acquiescing in the Action's rejection of these dependent claims, Applicants respectfully submit that claims 5-10 are patentable over Makiej in view of Weinstein and further in view of Marand and request that these rejections be withdrawn. Applicants expressly reserve the right to argue the separate patentability of one or more of these dependent claims in the future should the need arise.

III. Conclusion

The concerns of the Examiner addressed in full, Applicants respectfully request that the outstanding rejections be withdrawn and that a Notice of Allowance be issued forthwith. Should the Examiner have any questions regarding this application, Applicants encourage the Examiner to contact the undersigned, who can be reached at (919) 483-9024.

Respectfully submitted:

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